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09/996,475	11/20/2001	Vladislav Olchanski	58367.000003	2706

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Thomas E. Anderson, Esq.
Hunton & Williams
1900 K Street, N.W.
Washington, DC 20006-1109

EXAMINER

TANG, KAREN C

ART UNIT	PAPER NUMBER
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2151

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/996,475	Applicant(s) OLCHANSKI ET AL.	
	Examiner KAREN C. TANG	Art Unit 2151	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

- A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/14/08 has been entered.
- Claims 1-30 are presented for further examination.

Response to Arguments

1. Applicant's arguments filed 1/14/08 have been fully considered but they are not persuasive.

Affidavit

2. The affidavit filed on 05/25/07 under 37 CFR 1.131 *again*, has been considered but is ineffective to overcome the Menzie et al. reference.

The declaration filed on 05/25/07 fails to provide evidence to support the indicated claim of conception prior to the effective date of the Menzie reference. The evidence is not enough to satisfy issues of diligence or conception reduction to practice or an actual reduction to practice.

3. Applicant is attempt to prove the invention by showing conception before May 15, 2000 (the effective date of Menzie) before that date until Nov 20, 2001, the date of filing of this application.

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4. The evidence submitted is *insufficient* to establish a conception of the invention prior to the effective date of the Menzie reference. While conception is the mental part of the inventive act, it must be capable of proof, such as by demonstrative evidence or by a complete disclosure to another. Conception is more than a vague idea of how to solve a problem. The requisite means themselves and their interaction must also be comprehended. See *Mergenthaler v. Scudder*, 1897 C.D. 724, 81 O.G. 1417 (D.C. Cir. 1897). The exhibit does not demonstrate the evidence or proof in showing that the claimed conception took place. *Applicant has not yet support each of claim element with the affidavit to demonstrate conception.* Applicant must point out where each claimed limitation is according to the affidavit on record.

Applicant has provided the same 23 pages from the affidavit for mapping all the limitations without explaining how these pages are relevant to the claim limitations. Applicant needs to map the limitation by point to a specific page and line number on the affidavit in order to demonstrate the conception. Applicant needs to also apply the mapping on all the dependent claims, or else the depending claims cannot receive the benefit of priority date supported by the affidavit.

5. Applicant has not demonstrated the reasonable diligence from the period of **May 15, 2000, to November 21, 2000.**

6. Applicant has not demonstrated the reasonable diligence from the period of **November 30, 1998, to March 31, 1999.**

7. Applicant has not demonstrated the reasonable diligence from the period of **March 1999, to July 2000.**

8. Applicant has not demonstrated the reasonable diligence from the period of **August 4, 1999, to September 24, 2000.**

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2138.06 [R-1] "Reasonable Diligence"

The diligence of 35 U.S.C. 102(g) relates to rea-sonable "attorney-diligence" and "engineering-diligence" (*Keizer v. Bradley*, 270 F.2d 396, 397, 123 USPQ 215, 216 (CCPA 1959)), which does not require that "an inventor or his attorney ... drop all other work and concentrate on the particular invention involved...." *Emery v. Ronden*, 188 USPQ 264, 268 (Bd. Pat. Inter. 1974).

CRITICAL PERIOD FOR ESTABLISHING DILIGENCE BETWEEN ONE WHO WAS FIRST TO CONCEIVE BUT LATER TO REDUCE TO PRACTICE THE INVENTION

The critical period for diligence for a first conceiver but second reducer begins not at the time of conception of the first conceiver but just prior to the entry in the field of the party who was first to reduce to practice and continues until the first conceiver reduces to practice. *Hull v. Davenport*, 90 F.2d 103, 105, 33 USPQ 506, 508 (CCPA 1937) ("lack of diligence from the time of conception to the time immediately preceding the conception date of the second conceiver is not regarded as of importance except as it may have a bearing upon his subsequent acts"). What serves as the entry date into the field of a first reducer is dependent upon what is being relied on by the first reducer, e.g., conception plus reasonable diligence to reduction to practice (*Fritsch v. Lin*, 21 USPQ2d 1731, 1734 (Bd. Pat. App. & Inter. 1991), *Emery v. Ronden*, 188 USPQ 264, 268 (Bd. Pat. Inter. 1974)); an actual reduction to practice or a constructive reduction to practice by the filing of either a U.S. application (*Rebstock v. Flouret*, 191 USPQ 342, 345 (Bd. Pat. Inter. 1975)) or reliance upon priority under 35 U.S.C. 119 of a foreign application (*Justus v. Appenzeller*, 177 USPQ 332, 339 (Bd. Pat. Inter. 1971) (chain of priorities under 35 U.S.C. 119 and 120, priority under 35 U.S.C. 119 denied for failure to supply certified copy of the foreign application during pendency of the application filed within the twelfth month)).

THE ENTIRE PERIOD DURING WHICH DILIGENCE IS REQUIRED MUST BE ACCOUNTED FOR BY EITHER AFFIRMATIVE ACTS OR ACCEPTABLE EXCUSES

An applicant must account for the entire period during which diligence is required. *Gould*

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v. Schawlow, 363 F.2d 908, 919, 150 USPQ 634, 643 (CCPA 1966) (Merely stating that there were no weeks or months that the invention was not worked on is not enough.); *In re Harry*, 333 F.2d 920, 923, 142 USPQ 164, 166 (CCPA 1964) (statement that the subject matter “was diligently reduced to practice” is not a showing but a mere pleading). A 2-day period lacking activity has been held to be fatal. *In re Mulder*, 716 F.2d 1542, 1545, 219 USPQ 189, 193 (Fed. Cir. 1983) (37 CFR 1.131 issue); *Fitzgerald v. Arbib*, 268 F.2d 763, 766, 122 USPQ 530, 532 (CCPA 1959) (Less than 1 month of inactivity during critical period. Efforts to exploit an invention commercially do not constitute diligence in reducing it to practice. An actual reduction to practice in the case of a design for a three-dimensional article requires that it should be embodied in some structure other than a mere drawing.); *Kendall v. Searles*, 173 F.2d 986, 993, 81 USPQ 363, 369 (CCPA 1949) (Diligence requires that applicants must be specific as to dates and facts.).

The period during which diligence is required must be accounted for by either affirmative acts or acceptable excuses. *Rebstock v. Flouret*, 191 USPQ 342, 345 (Bd. Pat. Inter. 1975); *Rieser v. Williams*, 225 F.2d 419, 423, 118 USPQ 96, 100 (CCPA 1958) (Being last to reduce to practice, party cannot prevail unless he has shown that he was first to conceive and that he exercised reasonable diligence during the critical period from just prior to opponent’s entry into the field); *Griffith v. Kanamaru*, 816 F.2d 624, 2 USPQ2d 1361 (Fed. Cir. 1987) (Court generally reviewed cases on excuses for inactivity including vacation extended by ill health and daily job demands, and held lack of university funding and personnel are not acceptable excuses.); *Litchfield v. Eigen*, 535 F.2d 72, 190 USPQ 113 (CCPA 1976) (budgetary limits and availability of animals for testing not sufficiently described); *Morway v. Bondi*, 203 F.2d 741, 749, 97 USPQ 318, 323 (CCPA 1953) (voluntarily laying aside inventive concept in pursuit of other projects is generally not an acceptable excuse although there may be circumstances creating exceptions); *Anderson v. Crowther*, 152 USPQ 504, 512 (Bd. Pat. Inter. 1965) (preparation of routine periodic reports covering all accomplishments of the laboratory insufficient to show diligence); *Wu v. Jucker*, 167 USPQ 467, 472-73 (Bd. Pat. Inter. 1968) (applicant improperly allowed test data sheets to accumulate to a sufficient amount to justify interfering with equipment then in use on another project);

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Tucker v. Natta, 171 USPQ 494, 498 (Bd. Pat. Inter. 1971) (“[a]ctivity directed toward the reduction to practice of a genus does not establish, *prima facie*, diligence toward the reduction to practice of a species embraced by said genus”); *Justus v. Appenzeller*, 177 USPQ 332, 340-1 (Bd. Pat. Inter. 1971) (Although it is possible that patentee could have reduced the invention to practice in a shorter time by relying on stock items rather than by designing a particular piece of hardware, patentee exercised reasonable diligence to secure the required hardware to actually reduce the invention to practice. “[I]n deciding the question of diligence it is immaterial that the inventor may not have taken the expeditious course....”).

**WORK RELIED UPON TO SHOW REASONABLE DILIGENCE MUST BE
DIRECTLY RELATED TO THE REDUCTION TO PRACTICE**

The work relied upon to show reasonable diligence must be directly related to the reduction to practice of the invention in issue. *Naber v. Cricchi*, 567 F.2d 382, 384, 196 USPQ 294, 296 (CCPA 1977), *cert. denied*, 439 U.S. 826 (1978). >See also *Scott v. Koyama*, 281 F.3d 1243, 1248-49, 61 USPQ2d 1856, 1859 (Fed. Cir. 2002) (Activities directed at building a plant to practice the claimed process of producing tetrafluoroethane on a large scale constituted efforts toward actual reduction to practice, and thus were evidence of diligence. The court distinguished cases where diligence was not found because inventors either discontinued development or failed to complete the invention while pursuing financing or other commercial activity.); *In re Jolley*, 308 F.3d 1317, 1326-27, 64 USPQ2d 1901, 1908-09 (Fed. Cir. 2002) (diligence found based on research and procurement activities related to the subject matter of the interference

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count).< “[U]nder some circumstances an inventor should also be able to rely on work on closely related inventions as support for diligence toward the reduction to practice on an invention in issue.” *Ginos v. Nedelec*, 220 USPQ 831, 836 (Bd. Pat. Inter. 1983) (work on other closely related compounds that were considered to be part of the same invention and which were included as part of a grandparent application). “The work relied upon must be directed to attaining a reduction to practice of the subject matter of the counts. It is not sufficient that the activity relied on concerns related subject matter.” *Gunn v. Bosch*, 181 USPQ 758, 761 (Bd. Pat. Inter. 1973) (An actual reduction to practice of the invention at issue which occurred when the inventor was working on a different invention “was fortuitous, and not the result of a continuous intent or effort to reduce to practice the invention here in issue. Such fortuitousness is inconsistent with the exercise of diligence toward reduction to practice of that invention.” 181 USPQ at 761. Furthermore, evidence drawn towards work on improvement of samples or specimens generally already in use at the time of conception that are but one element of the oscillator circuit of the count does not show diligence towards the construction and testing of the overall combination.); *Broos v. Barton*, 142 F.2d 690, 691, 61 USPQ 447, 448 (CCPA 1944) (preparation of application in U.S. for foreign filing constitutes diligence); *De Solms v. Schoenwald*, 15 USPQ2d 1507 (Bd. Pat. App. & Inter. 1990) (principles of diligence must be given to inventor’s circumstances including skill and time; requirement of corroboration applies only to testimony of inventor); *Huelster v. Reiter*, 168 F.2d 542, 78 USPQ 82 (CCPA 1948) (if inventor was not able to make an actual reduction to practice of the invention, he must also show why he was not able to constructively reduce the invention to practice by the filing of an application).

DILIGENCE REQUIRED IN PREPARING AND FILING PATENT APPLICATION

The diligence of attorney in preparing and filing patent application inures to the benefit of the inventor. Conception was established at least as early as the date a draft of a patent application was finished by a patent attorney on behalf of the inventor. Conception is less a matter of signature than it is one of disclosure. Attorney does not prepare a patent application on behalf of particular named persons, but on behalf of the true inventive entity. Six days to execute and file application is acceptable. *Haskell v. Coleburne*, 671 F.2d 1362, 213 USPQ 192, 195 (CCPA 1982). See also *Bey v. Kollonitsch*, 866 F.2d 1024, 231 USPQ 967 (Fed. Cir. 1986) (Reasonable diligence is all that is required of the attorney. Reasonable diligence is established if attorney worked reasonably hard on the application during the continuous critical period. If the attorney has a reasonable backlog of unrelated cases which he takes up in chronological order and carries out expeditiously, that is sufficient. Work on a related case(s) that contributed substantially to the ultimate preparation of an application can be credited as diligence.).

Under 37 CFR 1.131, the critical period in which diligence must be shown begins just prior to the effective date of the reference or activity and ends with the date of a reduction to practice, either actual or constructive (i.e., filing a United States patent application). Note, therefore, that only diligence before reduction to practice is a material consideration. The "lapse of time between the completion or reduction to practice of an invention and the filing of an application thereon" is not relevant to an affidavit or declaration under 37 CFR 1.131. See *Ex parte Merz*, 75 USPQ 296 (Bd. App. 1947). Form paragraph 7.62 (reproduced in MPEP § 715) may be used to respond to a 37 CFR 1.131 affidavit where diligence is lacking.

9. The evidence submitted is insufficient to establish diligence from a date of conception to an actual reduction to practice. There is no information provided in the exhibits explicitly demonstrate diligence applied to reduce the method to practice.
10. The included Declaration fails to properly describe the events/dates between alleged conception (prior to May 15, 2000) and indicated Actual Reduction to Practice (November 21, 2001). Applicant's sole evident that demonstrate the diligent are the marketing agreement dated back in July 7, 2000, and a letter dated back in September 24, 2000, which indicates a "final

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documentation”, which did not particular indicate what documentation could it be. Not a single act in the affidavits had demonstrated during the critical period of May 15, 2000 and Nov 21, 2000 that discuss/show the element of claiming invention.

11. Applicant's arguments fail to comply with 37 CFR 1.111(b) because they amount to a general allegation that the claims define a patentable invention without specifically pointing out how the language of the claims patentably distinguishes them from the references.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Menzie et al hereinafter Menzie (US 6,650,932) in view of Bardy (US 2004/0044274) in further view of Seare et al hereinafter Seare (US 6,223,164).

14. Referring to Claims 1, 11, 19, 24, 25, 26, 27, 28, 29, and 30, Menzie discloses at least one processor readable medium (refer to Col 5, Lines 12-30); instructions carried on the at least one processor readable medium (software program comprises instructions, process by processor, Col 5, Lines 12-30); wherein the instructions are configured to be readable from the at least one

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medium by at least one processor and thereby cause at least one processor to operate so as to: (refer to Col 4, Lines Col 5 and Col 18, Lines 35-55); Collecting outcomes data sets for one or more indicators (analytical data, refer to Col 4, Lines 54-56) associated with one or more medical procedures (testing for autonomic nervous system, refer to Col 1, Lines 24) for a plurality of patients via one or more user interface (system is able to collect numerous patients/individuals information, Col 10, Lines 40-60, plurality of devices via the interface is able to collect per patient's information, refer to Col 4, Lines 1-15 and Col 4, Lines 37-39 and user interface, Col 4, lines 51) located at one or more user entities (refer to Col 3, Lines 67); converting at least some of the outcomes data sets for the one or more indicators associated with one or more medical procedures for the plurality of individuals into one outcomes results (refer to Col 2, Lines 8-30 and Col 4, Lines 53-67, and Col 5, Lines 1-7); establishing a norm (refer to Col 7, Lines 30-31 and refer to Col 2, Lines 25-60 and Col 6, Lines 60-67 and Col 7, Lines 1-35); comparing a selected one of the at least one outcomes result to the norm (refer to Col 6, Lines 29-36 and 60-67, and Col 7, Lines 1-30); generating at least one outcomes monitoring report comprising the selected one of the at least one outcomes result and the norm (the result is able to view via a web browser, refer to Col 4, Lines 14-15).

Although Menzie disclosed the invention substantially as claimed, Menzie is silent in regarding “establishing a norm based at least in part on an outcomes data group, the outcomes data group comprising a plurality of the outcomes data sets for the one or more indicators associated with one of the one or more medical procedures for the plurality of individuals”

Bardy, in analogous art, disclosing “establishing a norm based at least in part on an outcomes data group, the outcomes data group comprising a plurality of the outcomes data sets for the one

or more indicators associated with one of the one or more medical procedures for the plurality of individuals”(refer to 0067).

Hence, providing functionalities disclosed by Bardy, would be desirable for a user to implement in order to provide a convenience mechanism for user to assess medical services utilization in order to determine the best treatment for patients (refer to Seare, Col 4, Lines 26-67).

Therefore, at the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the system of Menzie by including the features presented by Bardy.

15. Referring to Claims 2 and 12, Menzie discloses transmitting the at least two outcomes data sets for one or more indicators associated with the one of the one or more medical procedures for the plurality of individuals to a data processor (refer to Col 2, Lines 8-31, Col 4, Lines 50-67).

16. Referring to Claims 3, 5, 13, 15, and 21, Menzie discloses selectively restricting access to the at least one outcomes monitoring report (refer to Col 11, Lines 5-30).

17. Referring to Claims 4, and 14 and 20, Menzie posting the at least one outcomes monitoring report over the webpage (refer to Col 4, Lines 14).

18. Referring to Claim 6, Menzie discloses collecting the at least two outcomes data sets associated with the one or more medical procedures from at least one user entity at a plurality of

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discrete intervals (refer to Col 14, Lines 39-50 and 65-67 and Col 15, Lines 3-10 and Lines 40-67 and Col 16, Lines 1-26 and Lines 60-64 and Col 18, Lines 1-8).

19. Referring to Claim 7, Menzie discloses generating the at least one outcomes monitoring report from the plurality of discrete intervals (refer to Col 2, Lines 21-25).

20. Referring to Claims 8 and 16, Menzie discloses collecting the outcomes data sets for the one or more indicators (analytical data, refer to Col 4, Lines 54-56) associated with the one or more medical procedures for the plurality of individuals located at the one or more user entities (testing for autonomic nervous system, refer to Col 1, Lines 24), individually identifying and converting the outcomes data sets for the one or more indicators associated with the one of the one or more medical procedures for the plurality of individuals located at each user entity of the one or more entities (refer to Col 2, Lines 8-30 and Col 4, Lines 53-67, and Col 5, Lines 1-7), and wherein the outcomes data sets for the one or more indicators associated with the one of the one or more medical procedures for the plurality of individuals located at the one or more user entities comprises the outcomes data group (refer to Col 3, Lines 67).

21. Referring to Claim 9 and 17, Menzie discloses wherein the at least one outcomes monitoring report includes at least one outcomes result for a selected user entity of the one or more user entities and at least one comparison of the norm to the least one outcomes result for the selected user entity (refer to Col 4, Lines 1-15 and Col 6, Lines 20-45).

22. Referring to Claims 10, and 18, Menzie discloses at least one processor readable medium for storing a computer program of instructions configured to be readable by at least one processor for instructing the at least one processor to execute a computer process for performing the method as recited in claim 1 (refer to Col 2, Lines 28-48 and Col 4, Lines 50-64).

23. Referring to Claim 23, Menzie discloses wherein the surgical procedures outcomes dataset are primary source data sets (refer to Col 2, Lines 8-27).

Conclusion

Examiner's Notes: Examiner has cited particular columns and line numbers in the references applied to the claims above for the convenience of the applicant. Although the specified citations are representative of the teachings of the art and are applied to specific limitations within the individual claim, other passages and figures may apply as well. It is respectfully requested from the applicant in preparing responses, to fully consider the references in entirety as potentially teaching all or part of the claimed invention, as well as the context of the passage as taught by the prior art or disclosed by the Examiner. In the case of amending the claimed invention, Applicant is respectfully requested to indicate the portion(s) of the specification which dictate(s) the structure relied on for proper interpretation and also to verify and ascertain the metes and bounds of the claimed invention.

A shortened statutory period for reply to this Office action is set to expire THREE MONTHS from the mailing date of this action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen C. Tang whose telephone number is (571)272-3116. The examiner can normally be reached on M-F 7 - 3.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Follansbee can be reached on (571)272-3964. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/K. C. T./

Examiner, Art Unit 2151

/John Follansbee/

Supervisory Patent Examiner, Art Unit 2151